

Translation

PATENT COOPERATION TREATY

PCT/JP2003/011046



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference GP03-1026PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/011046	International filing date (day/month/year) 29 August 2003 (29.08.2003)	Priority date (day/month/year) 30 August 2002 (30.08.2002)
International Patent Classification (IPC) or national classification and IPC A61K 45/00, A61P 3/10// C07K 7/06, C12N9/64		
Applicant CELESTAR LEXICO-SCIENCES, INC.		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☒ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) 1, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
- This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

Date of submission of the demand 24 March 2004 (24.03.2004)	Date of completion of this report 29 July 2004 (29.07.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/011046

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 58-63, 67-72, 83-84, 91

because:

- ☒ the said international application, or the said claims Nos. 58-63, 67-72, 83-84 relate to the following subject matter which does not require an international preliminary examination (*specify*):

The inventions of claims 58-63, 67-72, and 83-84 concern a method for treating the human body by therapy, which does not require an international preliminary examination by the International Preliminary Examining Authority in accordance with PCT Article 34(4)(a)(i) and Rule 67.1(iv).

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claim No. 91 is so unclear that no meaningful opinion could be formed (*specify*):

The compound in the description of claim 91 is specified by the expression "identification method described in any of claims 86 to 90." This description encompasses all compounds and medicinal compositions obtained by that identification method. However, no specific compounds obtained by this identification method are described in the Specification. Therefore, claim 91 lacks full disclosure in the sense of PCT Article 5 and lacks support by the specification in the sense of PCT Article 6. In addition, when the level of technology at the time of filing is considered, it is entirely unclear what kinds of compounds are specifically included and what kinds of compounds are not included, and therefore the above claim is unreasonably vague and does not satisfy the requirement for clarity stipulated in Article PCT 6. As a result, no judgment can be rendered concerning the invention described in the above claim.

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for said claims Nos. 58-63, 67-72, 83-84, 91.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ see Supplemental Box for further details.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-57, 64-66, 73-82, 85-90, 92-94	YES
	Claims		NO
Inventive step (IS)	Claims	1-57, 64-66, 73-82, 85-90, 92-94	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-57, 64-66, 73-82, 85-90, 92-94	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: Proc Natl Acad Sci USA. 2001 Dec, Vol. 98, No. 25, p. 14189-91.
Document 2: J Biol Chem. 1994 Feb, Vol. 269, No. 8, p. 5712-9.
Document 3: Nucleic Acids Res. 1993 Nov, Vol. 21, No. 22, p. 5092-100.
Document 4: J Biol Chem. 1984 Oct, Vol. 259, No. 20, p. 12489-9

The inventions described in claims 1-57, 64-66, 73-82, 85-90, and 92-94 involve an inventive step with respect to documents 1-4 cited in the international search report. Documents 1-4 do not describe either carbohydrate metabolism-associated gene transcription factors or their relationship to calpain. Moreover, persons skilled in the art cannot easily conceive of such matters.

Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
- a. type of material
- ☒ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☐ in written format
- ☒ in computer readable form
- c. time of filing/furnishing
- ☐ contained in the international application as filed
- ☒ filed together with the international application in computer readable form
- ☐ furnished subsequently to this Authority for the purpose of search and/or examination
- ☐ received by this Authority as an amendment* on _____
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. 1 applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".